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Marshall O'Toole Gerstein Murray & Borun 6300 Sears Tower 233 South Wacker Drive Chicago, IL 60606-6402			WANG, SHENGJUN	
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The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES W. WILLIAMS, ANITA CHONG,
and W. JAMES WALDMAN

Appeal 2009-000280
Application 09/529,053
Technology Center 1600

Oral Hearing Held: Wednesday, July 8, 2009

Before DEMETRA J. MILLS, ERIC GRIMES and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

LI SIEN, ESQ.
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The above-entitled matter came on for hearing on Wednesday, July 8, 2009, commencing at 1:02 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Laurie B. Allen, Notary Public.

1 JUDGE MILLS: Just to let you know, we are familiar with the facts
2 of your invention and the issues of the case. And you have 20 minutes you
3 can spend however you like, but it would be most helpful to us if you would
4 focus on your best argument, what you consider to be the critical issues.
5 Thank you.

6 MS. HSIEN: Okay. Good. I take it the Examiner is not appearing?

7 JUDGE MILLS: No.

8 MS. HSIEN: Okay. Well, really, there are two main issues. The first
9 one is whether the claims that recite combinations of the Leflunomide
10 product, which for purposes of this appeal we are assuming have antiviral
11 activity, and that was known in the art. A combination of a Leflunomide
12 product with a pyrimidine compound that supplies cytidine, uridine or
13 thymidine, so it enhances serum levels. It has to be significant enough to do
14 that of these natural, occurring, pyrimidine nucleotides where that
15 combination is not obvious. And, so that's one issue.

16 The second issue is whether a claim that recites combining
17 Leflunomide product with pyrimidines that don't have antiviral activity is
18 new matter. The Examiner has acknowledged that that is not obvious, but
19 thinks that it adds new matter. So, we're hoping that one or the other, or
20 maybe both of these claims, are going to be allowable.

21 With respect to the first claim, the enhancing serum levels as cited in
22 uridine and thymidine, the Examiner has supplied a couple of prior art
23 references that refer to unnatural nucleotide analogs that are used to treat
24 AIDS. The problem is that when you combine the Leflunomide product
25 with these pyrimidines that are unnatural and have antiviral activity, even
26 that accommodation doesn't get you to the claim language, because the claim

1 language by its nature excludes the unnatural analogs because they don't
2 supply serum levels of uridine, cytidine or thymidine.

3 And, the Examiner, we pressed him for proof of his proposition,
4 which was that these antiviral agents do supply natural pyrimidine
5 nucleotides, and he didn't provide any. In contrast, we did have some
6 evidence and our Atwood Declaration, which is page B3 of the appendix.
7 So paragraph 8 of Atwood Declaration, this is an expert in the field, and he's
8 providing us evidence as to what one of ordinary skill in the art would
9 understand. He says that "The definition of pyrimidine compounds confirms
10 that the contemplative pyrimidine compounds would not have antiviral
11 activity."

12 And then in paragraph 10, item B, it says "The definition of
13 pyrimidine compound excludes pyrimidine compounds with antiviral
14 activity." So I think that we have actually provided evidence that analogs,
15 which are administered for the purpose of being incorporated into DNA and
16 messing up RNA synthesis of viruses couldn't possibly meet the limitation
17 of our claims.

18 JUDGE GRIMES: The statements in the declaration don't specifically
19 say that the pyrimidine analogs that are in the prior art wouldn't be
20 metabolized into naturally occurring pyrimidines. Do they? I mean, does
21 the declaration say that?

22 MS. HSIEN: The declaration doesn't say that in so many words, but it
23 does say.

24 JUDGE GRIMES: It says that "Naturally occurring pyrimidines
25 would not have antiviral activity."

26 MS. HSIEN: Yes.

1 JUDGE GRIMES: Not that pyrimidines with antiviral activity could
2 not provide some naturally occurring pyrimidines. Right? Isn't it the
3 Examiner's position that the pyrimidine analogs that are in the prior art
4 would be expected to provide intermediates to pyrimidine synthesis because
5 they have a pyrimidine?

6 MS. HSIEN: I think that is the Examiner's position. I think he is
7 reading the claim to say "pyrimidine compound." I don't think he's
8 necessarily reading the claim to say pyrimidine compound that supplies
9 increased serum levels of uridine, cytidine and thymidine. And, you know,
10 he is entitled to read it broadly, but he is not entitled to read it to encompass
11 something that can't possibly be true.

12 He did provide evidence that when you give AIDS drugs, they
13 actually do interfere with DNA synthesis and you get toxic effects, and that
14 they do not supply naturally occurring pyrimidine nucleotides. And I think
15 that when you challenge the Examiner on a fact they do have an obligation
16 to come back with evidence that supports their theory. Simply because it's a
17 speculative idea that it might be true, doesn't mean that in fact it is true. And
18 when we provided evidence that suggests otherwise, I think he does have an
19 obligation to provide some definite evidence.

20 JUDGE LEBOVITZ: What evidence suggests otherwise?

21 MS. HSIEN: I think you can infer from the Atwood Declaration,
22 although you're right. It doesn't say so in so many words. You can infer that
23 analogs, which do have an antiviral effect, do not supply uridine, cytidine
24 and thymidine. It levels sufficient increase serum levels of those
25 nucleotides.

26

1 We also had other evidence showing that people who are given these
2 analogs suffer from deficiencies in pyrimidine levels. It's B14 and it says
3 that "AZT has cytotoxicity in human bone marrow progenitor cells."

4 JUDGE GRIMES: Which reference is that?

5 MS. HSIEN: It is Sommadossi et al.

6 JUDGE LEBOVITZ: Where are you reading from?

7 MS. HSIEN: The Abstract: "We evaluated the effects of natural
8 purine and pyrimidine nucleotides and protection from or reversal of AZT
9 cytotoxicity." So, because these unnatural analogs don't supply or interrupt,
10 rather, the pyrimidine pathways, they don't increase serum levels of uridine,
11 cytidine or thymidine, and they would be expected to have no effect in
12 helping the toxicity of Leflunomide product. So, in other words, our
13 invention is that if we supply natural pyrimidines, we can reduce toxicity
14 associated with Leflunomide.

15 JUDGE LEBOVITZ: I'm sorry. Where were you reading from when
16 you were reading about the AZT?

17 MS. HSIEN: Oh, it was page B.

18 JUDGE LEBOVITZ: Of which reference?

19 MS. HSIEN: Sommadossi, B14. And with respect to the other issue
20 in the case, which is whether there is new matter with respect to pyrimidines
21 that don't have antiviral activity, I think we did provide declaratory evidence
22 to that effect and there is case law saying that where there is an inherent
23 property that must necessarily be an inherent property of the claimed device
24 of the claimed method or the claimed composition that inherent property can
25 be added into the claims. And I think we've shown with the declaratory
26

1 evidence that in fact compounds that supply natural pyrimidines don't have
2 antiviral effect.

3 I'd also like to point you to a passage in the application that supports
4 the idea that there are pyrimidines that do and pyrimidines that don't have
5 antiviral activity. And that would be page 17 of the specification, line 17.

6 JUDGE GRIMES: I'm sorry. That's evidence of what?

7 MS. HSIEN: Oh, well, to the extent that the invention says that you
8 can combine Leflunomide product with antiviral agents, and among these
9 antiviral agents are some of the very unnatural analogs that the Examiner has
10 cited in the prior art. And it lists, for example, at line 21 of page 17. It says,
11 "Zidovudine, didanosine, or zalcitabine." Those were analogs that were
12 described in the Hammer reference. So the extent that we described the
13 genus of pyrimidines, some of which have antiviral activity and some of
14 which don't, we are permitted to carve out with a negative limitation the
15 types of pyrimidines that do have antiviral activity.

16 So I think that claim 46 that recites "administering a pyrimidine
17 compound without antiviral activity" is properly entered as not new matter
18 for either one of those reasons. One is because it describes an inherent
19 property of the pyrimidine compounds that we contemplated using, or
20 because it describes a subspecies of pyrimidine compounds that we were
21 permitted to carve out of the application as a negative limitation.

22 JUDGE MILLS: So as we understand your overall argument is that
23 the pyrimidine analogs in the prior art do not function to enhance their own
24 levels of uridine, cytidine and thymidine?

25 MS. HSIEN: Yes, that's correct. Yes. Thank you.

26

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1 JUDGE MILLS: I don't believe we have any other questions for you.

2 MS. HSIEN: Thank you.

3 (Whereupon, at 1:20 p.m., the proceedings were concluded.)

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